PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 229-204-WO	**FOR FURTHER ACTION**	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/DK 03/00768	International filing date *(day/month/year)* 10.11.2003	Priority date *(day/month/year)* 21.11.2002
International Patent Classification (IPC) or both national classification and IPC C07C275/00		
Applicant NEUROSEARCH A/S		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 5 sheets, including this cover sheet.

   ☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the opinion
   - II ☐ Priority
   - III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
29.05.2004	11.01.2005
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized Officer Breimaier, W Telephone No. +49 89 2399-8327

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/DK 03/00768

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:

Description, Pages

1-28 as originally filed

Claims, Numbers

1-33 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

   These elements were available or furnished to this Authority in the following language: , which is:

   ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).

   ☐ the language of publication of the international application (under Rule 48.3(b)).

   ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

   ☐ contained in the international application in written form.

   ☐ filed together with the international application in computer readable form.

   ☐ furnished subsequently to this Authority in written form.

   ☐ furnished subsequently to this Authority in computer readable form.

   ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

   ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

   ☐ the description, pages:

   ☐ the claims, Nos.:

   ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

   (Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claims Nos. 1-10, 21-25, 27, 28, 33

because:

☒ the said international application, or the said claims Nos. 33 relate to the following subject matter which does not require an international preliminary examination (specify):

see separate sheet

☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. are so unclear that no meaningful opinion could be formed *(specify)*:

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for the said claims Nos. 1-10, 21-25, 27, 28

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/ or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the Standard.

☐ the computer readable form has not been furnished or does not comply with the Standard.

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	12-14, 29-33
	No:	Claims	1-11, 15-28
Inventive step (IS)	Yes:	Claims	
	No:	Claims	12-14, 29-33
Industrial applicability (IA)	Yes:	Claims	1-32
	No:	Claims	33 ?

2. Citations and explanations

see separate sheet

Re Item III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The aryl ureido derivatives of general formula (I) according to claim 1 is so generally formulated that no reasonable search has been carried out (see ISA/210). As Claims 1-10, 21-25, 27 and 28 have not been searched, a substantive examination cannot be carried out.

Claim 33 relate to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT. Consequently, no opinion will be formulated with respect to the industrial applicability of the subject-matter of these claims (Article 34(4)(a)(I) PCT).

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

novelty

Although a substantive examination cannot be carried out (see under item III), the following citations have to be taken into consideration in order to file a new set of claims.

The subject-matter according to claims 1-11 and 15-28 is not novel pursuant to Art. 33(2) PCT having regard to the cited documents D1-D11.

In particular it is referred to:

D1 (WO 00/24707), claims 1 and 2 and pp. 10 and 11;
D2 (WO 98/47879), general formula (I) and examples;
D3 (WO 99/38846), general formulae (III)/(IX) and examples on pp. 31-33;
D4 (WO 99/00357), general formula (I) and examples 124, 125 in table 1;
D5 (US-A 6 417 393), general formula (I), claim 1 and examples;
D6 (WO 02/39987), general formulae (I)/(II), pp. 8-15, examples;
D7 (CA XP002277267), tetrazolyl substituted phenyl ureido derivative;
D8 (CA XP002277268), carboxyl substituted phenyl ureido derivatives;
D9 (US-A 2 722 544), sulfonyl substituted phenyl ureido derivatives, examples;
D10 (GB-A 709 455), sulfonyl substituted phenyl ureido derivatives, examples;
D11 (WO 97/29743), general formula (I), pp. 3 and 5 with claims 1 and 11.

The subject-matter according to claims 12-14 and 29-33 is considered to be novel pursuant to Art. 33(2) PCT since none of the above documents discloses aryl ureido derivatives of the present general formula (V) as well as the use of the aryl ureido benzoic acid derivatives as a medicament for treating diseases or disorders responsive to modulation of an aspartate or a glutamate receptor.

inventive step

The subject-matter according to claims 12-14 and 29-33 seems not to be based on an inventive step pursuant to Art. 33(3) PCT.

At present it is doubtful whether the problem posed (provision of alternative urea derivatives for treating Parkinsons, Alzheimers disease, stroke, shock, psychosis etc. in view of e.g. D11, p. 113; WO 94/22807, cited on present page 1, l. 30; EP-A 0 656 350 (D12), pp. 7/8 and J.Med.Chem., 33, 1990, pp. 854-861 (D13), table (I)) is indeed solved. No data are available from the application documents which show that the phenyl carbamoyl indazole derivatives of general formula (V) exhibit the desired efficacy. In table 1 only sulfonyl and carboxyl substituted urea derivatives have been tested. Thus, in the absence of any data, an inventive step cannot be acknowledged.

industrial applicability

For the assessment of the present claim 33 on the question whether they are industrially applicable, no unified criteria exist in the PCT Contracting States. The patentability can also be dependent upon the formulation of the claims. The EPO, for example, does not recognize as industrially applicable the subject-matter of claims to the use of a compound in medical treatment, but may allow, however, claims to a known compound for first use in medical treatment and the use of such a compound for the manufacture of a medicament for a new medical treatment.

further remarks

a. It is noted that, when filing a new set of claims, in order for the present aryl ureido alternatives to be regarded as uniform (Rule 13.1 PCT) a significant structural element which is shared by all the alternatives should constitute a structurally distinctive portion in view of the available prior art.

b. Contrary to the requirements of Rule 5.1(a)(ii) PCT, the documents D11-D13 are not suitably cited in the description.